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Original Article

Screening for fear of cancer recurrence: Instrument validation and current status in early stage lung cancer patients

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Background: Fear of cancer recurrence (FCR) is one of the most distressing concerns for cancer patients. A psychometrically validated brief scale is urgently needed for use in busy clinical oncology settings. This study aimed to (1) develop and validate the 7-item fear of cancer recurrence scale Chinese version (FCR7-C), and (2) explore the severity of FCR in post-operative early-stage lung cancer patients in Taiwan.

Methods: Early-stage lung cancer patients were recruited from a medical center in Taiwan. The FCR7-C was evaluated for content and construct validity and internal consistency reliability. Construct validity of FCR7-C was determined by the empirically supported correlation and confirmatory factor analysis (CFA).

Results: A total of 160 subjects were recruited. The FCR7-C was shown to have satisfactory content validity and internal consistency reliability (Cronbach's $\alpha = 0.9$). The unidimensional structure was confirmed by CFA that showed a good fit for the model. The FCR7-C score correlates positively with the degree of most of the physical symptoms, anxiety, and depression, but correlates negatively with patient age, performance status, and quality of life. We found that 81.9% of patients reported at least some FCR, with a mean FCR severity of 15.18 (SD = 7.78).

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Conclusion: FCR7-C is a brief screening tool with good psychometrics. Patients with early-stage lung cancer still revealed mild to moderate level of FCR. Applying the FCR7-C for to screen cancer patients' distress and further develop personalized psychological interventions would be strongly suggested.

Introduction

Fear of Cancer Recurrence (FCR) is defined as the emotional distress caused by the concern that cancer will return or progress after anti-cancer treatment. FCR is prevalent among cancer survivors.[1,2] Generally, severity of FCR is also known as level of patients' FCR experience. Severe FCR can interfere with a patient's ability to move forward with their life and to plan for the future.[3,4] Patients with severe FCR may experience sleep disturbances,[5] anxiety and depression,[6–9] and poor quality of life (QOL)[10–12] and may require more health care services.[13] Thus, the assessment of FCR in cancer survivors is important. However, relatively few assessment tools have been developed to be used in Chinese population, such as in Taiwan, China, Hong Kong, and across the world. Thus, there is limited information about the severity of Chinese cancer patients' concerns about disease recurrence.

Numerous FCR assessments have been developed over the past decade.[14] For example, the comprehensive 42-item multidimensional Fear of Cancer Recurrence Inventory covers multiple domains of FCR in detail[8] and has been widely used to assess FCR in cancer patients[15] and their caregivers.[16] However, given the burden on patients by repeated assessments during cancer follow-up and the time constraints in the clinical setting, a brief yet accurate scale would better serve patients and clinicians.

The 7-item unidimensional Fear of Cancer Recurrence (FCR7) assessment was originally named the 'Fear of Recurrence'.[6] The FCR7 has been used to assess FCR in head and neck cancer patients. The FCR7 consists of 4 items to assess the level of worry about cancer recurrence, 2 items that measure the level of interference of FCR with the patient's thoughts and activities, and 1 item to assess the patient's behavioral response.[6,17] The overall scale represents the experiences of the level (severity) of patients' FCR.

To evaluate the psychometric properties of the FCR7, the construct validity has been examined by determining whether the assessment took into account the factors known to affect FCR severity.[1,10,18–20] For example, more severe FCR tends to occur in younger patients[1,18] and in those with poor physical status.[1] More severe FCR is also closely linked to higher anxiety and depression.[18,19] Physical symptoms may increase the FCR by reminding patients about their physical status and the possibility of cancer recurrence.[20–22] Patients with more severe FCR report a lower quality of life.[10]

Together, based on the evidence presented above, the following predictions regarding correlations between the Chinese version of FCR7 (FCR7-C) score and related parameters were made: (1) The FCR7-C score will correlate positively with cancer-related symptoms (pain, fatigue, nausea/vomiting, dyspnea, insomnia, lack of appetite, constipation, and diarrhea), depression, and anxiety; and (2) The FCR7-C score will correlate negatively with patient age, performance status, and overall QOL. In addition, the FCR7-C should reflect the uni-dimensional design of the original FCR7.[17]

We chose early-stage lung cancer patients to assess the effectiveness of FCR7-C because FCR may be common among patients with lung cancer due to its high mortality.[23] Previous studies report a high prevalence of FCR (72%) among patients with lung cancer[24] and more severe FCR in patients with lung cancer than with other types of cancer.[8] Although screening methods for earlier detection of lung cancer[25] have improved the 5-year survival rate of early-stage lung cancer (40—70%) in Taiwan,[26,27] the reputation of lung cancer as a deadly disease may induce particular fear.

To establish an effective assessment for FCR in Chinese-speaking cancer patients, this study aimed to (1) translate and develop the FCR-7 into Chinese (step I), and (2) examine the psychometrics of the FCR7-C and explore the severity of FCR in operable early-stage lung cancer patients (step II).

Methods

Step 1: Translation, development and examination of content validity

After obtaining permission from the original authors to use the FCR7[6], the instrument was translated into Chinese and the accuracy of Chinese translation was confirmed by back-translating between English and Chinese based on the instrument translation principles.[28] The content validity of FCR7-C was examined and discussed by 5 experts (2 oncologists, 2 psycho-oncology nurse researchers, and one master-prepared oncology nurse), who found that FCR7-C is satisfactory.

For face validity (from patients), we recruited 10 lung cancer patients from the thoracic surgery outpatient clinic in a medical center in Northern Taiwan. Eligible subjects were adult patients who (i) were diagnosed with early-stage lung cancer (stages I, II, & IIIA), (ii) had undergone tumor resection surgery, (iii) were currently disease-free, and (iv) were able to communicate in Chinese or Taiwanese. IRB approval (IRB number: 201012108RC) and patients' consents were obtained before data collection.

All of the 10 patients reported that the FCR7-C reflected their fears of cancer recurrence and that it was easy to understand and answer. Thus, the face validity of FCR7-C was well supported by the patients.

Step II: Examination of the reliability and construct validity of the FCR7-C

In step II, the same recruitment criterion and settings were applied. We assessed the internal consistency reliability using the calculated Cronbach's alpha value. Construct validity was examined in 2 ways: (1) testing the correlation between assumptions and actual outcomes with respect to FCR7-C variables, and (2) conducting confirmatory factor analysis (CFA) to verify the dimensionality of the FCR7-C. The goal of using CFA, rather than using exploratory factor analysis (EFA), is that "CFA model is specified in advance and being evaluated by goodness of fit and the interpretability and strength of the parameters".[29] Thus, in this study, we applied CFA to verify the FCR7-C as its assumed one-factor structure (uni-dimensional scale). Finally, after the validation, results of the severity of cancer recurrence would be also explored from the step II results in FCR7-C.

Measures

To compare theoretical and actual outcomes of the FCR7-C for selected variables, we used several tools, including the Karnofsky performance status (KPS),[30] 2 overall QOL items and the Symptom Subscale from the European Organization for Research and Treatment of Cancer QOL Questionnaire (version 3.0) (EORTC QLQ-30),[31] and the Hospital Anxiety and Depression Scale (HADS).[32]

Fear of Recurrence 7 (FCR7)

The original FCR7 questionnaire consists of 7 questions. The first 6 of these questions are scored on a 5-point scale. The scoring system is: '1 = not at all', '2 = a little', '3 = sometimes', '4 = a lot' and '5 = all the time'. The 7th item is used to assess the extent to which FCR interferes with the patient's thoughts and activities and is scored on a 10-point scale, with '0' indicating 'not at all' and '10' indicating 'a great deal.' For each individual item, a score $\geq$4 on questions 1 to 6 (ranging from 1 to 5), or $\geq$7 on question 7 (ranging from 0 to 10) indicates a significant level (severity) of fear of cancer recurrence[6] and suggests that the patient needs further help.[6]

Although there is no definite cut-off point to decide patients' FCR, the single item or total (sum) scores can be all used for preliminarily identifying patients' severity of FCR as the above scoring suggestion. The total score is ranged from 6 to 40, with higher the score indicating higher level of FCR.

Karnofsky performance scale (KPS)

The Karnofsky performance scale (KPS) was used to assess patients' ability to perform tasks of daily living. The possible score on this 11-item assessment ranges from 100 (fully normal function) to 0 (death).[30]

EORTC QLQ-30

Two overall QOL questions and the symptom subscale from the EORTC QLQ-C30 were incorporated into this assessment. The symptom subscale includes fatigue, pain, nausea, dyspnea, insomnia, lack of appetite, constipation, and diarrhea, each of which was rated using a 4-point Likert Scale (1, not at all; 4, very much). The original scores are then transformed to a 100-point scale score, with a higher score indicating better QOL.[31] The Taiwan Chinese version of the EORTC QLQ-C30 for lung cancer patients has been proven to be reliable and valid.[33] The Cronbach's alpha in this study was 0.91 for the overall EORTC QLQ-C30 symptom scale and 0.67—0.79 for each symptom.

Hospital Anxiety and Depression Scale (HADS)

Patient anxiety and depression levels were assessed using the HADS scale,[32] which consists of two subscales: anxiety and depression, and contains 7 items per subscale, with a maximum subscale score of 21 per subscale. A higher score indicates a higher level of anxiety or depression. Satisfactory psychometrics for the HADS has been reported in cancer-related studies in Taiwan.[34] In this study, the Cronbach's alpha for the anxiety and depression subscales was 0.83 and 0.70, respectively.

Background information form

Background information obtained included the patients' gender, age, education, marital status, religion, occupation, cancer stage, type of surgery, and time since diagnosis.

Statistical analysis

Internal consistency reliability was indicated by Cronbach's alpha coefficient. Construct validity was examined by confirmatory factor analysis to confirm the uni-dimensionality of the design. The CFA was examined using the Analysis of Moment Structure (AMOS), version 20. The goodness of fit for the model was evaluated by chi-square analysis (χ^2), the ratio of chi square to degrees of freedom (χ^2/df), and other commonly used indicators, including the root mean square of error approximation (RMSEA), standardized root mean-square residual (SRMR), normed-fit index (NFI), relative fit index (RFI), goodness of fit index (GFI), and relative fit index (RFI). The recommended cut-offs that indicate a good fit for RMSEA $<$0.08, SRMR$<$0.08, NFI$\geqq$0.95, GFI$\geqq$0.95, RFI$\geqq$0.95.[35] The modification index (MI) was used to determine the error correlations on parameter estimates of CFA if needed.[36]

Spearman's analysis of empirically supported correlations between FCR7-C and selected variables were examined for support of the construct validity. Variables investigated for correlation with FCR include patient age,[18] physical status,[1] severity of symptoms,[5,12,20] and level of psychological distress.[6,7,9,37] Finally, the FCR severity in early-stage lung cancer patients was determined by statistical analysis of the data.

The sample size was determined based several concerns.[38] These included (1) the effect of factors; (2) the effect of number of indicators; (3) effect of magnitude of factor loadings; and (4) the effect of magnitude of factor correlations. For example, the six-to eight-indicator, one factor model and loading 0.50 were associated with a minimum sample size of 90. The CFA in the current study, one factor model with seven indicators, and all the factor loading higher than 0.5 (ranging from 0.60 to 0.97) except one (0.40) suggest the sample size as 160 is enough.

Results

Patient characteristics

In step II, a total of 160 subjects were recruited for psychometric testing of FCR7-C and better representativeness for the severity of FCR in early-stage lung cancer patients. There were 87 females (54.4%) and 73 males (45.6%) and with a mean age of 61.5 years (SD, 11.9). The demographic data are presented in Table 1. The majority of the patients (83.1%) had a good performance status with KPS score (≥90) (Table 1).

Table 1 Background information of subjects (N = 160).

	n	%	Mean (SD)	Range
Sex				
Male	73	45.6		
Female	87	54.4		
Age (years)			61.5 (11.9)	30–87
Education level (years)			11.2 (5.1)	0–26
Illiterate	3	1.9		
Elementary school	46	28.7		
High school	49	30.5		
College and above	62	38.9		
Marital status				
Unmarried, divorced, widowed	23	14.4		
Married	137	85.6		
Religion				
Yes	127	79.4		
None	33	20.6		
Occupational status				
Employed	51	31.9		
Unemployed	77	48.1		
Unemployed since having cancer	32	20.0		
Cancer stage				
I	123	76.8		
II	14	8.8		
IIIA	23	14.4		
Surgery type				
Lobectomy	129	80.6		
Lobectomy + Wedge resection	15	9.4		
Wedge resection	13	8.1		
Sleeve resection	2	1.3		
Sleeve resection + Lobectomy	1	0.6		
Time since diagnosis (months)			8.9 (4.6)	3–19
3–6	66	41.2		
7–12	60	37.5		
>12	34	21.3		
Karnofsky performance score				
60	2	1.3		
70	4	2.5		
80	21	13.1		
90	78	48.7		
100	55	34.4		

The overall quality of life score (based on the EORTC QLQ-C30, the two overall items mean score in a 0–100 system) for this cohort was 66.8 (SD = 20.1). Patients generally reported to have low symptoms, with the top ranked symptom as dyspnea, sleep impairment and fatigue and mean scores as 24.2, 23.5, and 21.0, respectively.

Reliability

The Cronbach's alpha value for internal consistency reliability in the current study was 0.90 for the FCR7-C. In order to better know the item-quality of FCR7-C, we also examined item to total (scale) correlation. The generally suggested and acceptable item to total correlation values are 0.2, 0.3 or 0.4.[39] In our study, except item 6, the item to total correlation values were ranging from 0.72 to 0.85. Even for item 6, it had item to total correlation as 0.45 which met the criteria. We thus kept all the original items of FCR7. Taking together, the result of Cronbach's alpha as 0.9 and high item to total correlation strongly support that FCR7-C has a very good internal consistency reliability[40] (Table 2).

Construct validity

The standardized coefficients for items 1 through 7 ranged from 0.42 to 0.97 (Fig. 1). Since the goodness of fit of the model is not perfect, the MI was further applied to adjust the model. Chi-square value ($\chi^2 = 85.98$; $p < 0.001$) were found to be significant. The normed chi-square (χ^2/df) value

Table 2 Internal consistency reliability and item to total correlations (N = 160).

	FCR items	Item to Total Correlation	Alpha if Item Deleted
Q1	I am afraid that my cancer may recur	0.85	0.87
Q2	I am worried or anxious about the possibility of cancer recurrence	0.86	0.87
Q3	How often have you worried about the possibility of getting cancer again?	0.84	0.87
Q4	I get waves of strong feelings about the cancer coming back	0.72	0.89
Q5	I think about the cancer returning when I did not mean to	0.81	0.88
Q6	I examine myself to see if I have physical signs of cancer	0.45	0.91
Q7	To what extent does worry about getting cancer again spill over or intrude on your thoughts and activities	0.76	0.91

Note: Overall Cronbach's alpha = 0.90.

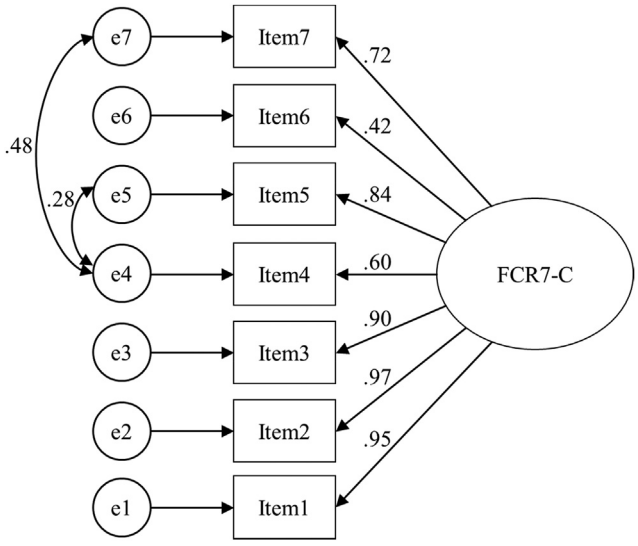

Figure 1 Results of confirmatory factor analysis of the FCR7-C.

was determined to be 2.4, which is an acceptable level. The RMSEA index was 0.09, indicating a mediocre fit. Additional indices, including the SRMR (0.04), NFI (0.97), RFI (0.95), and the GFI (0.95), support a good fit. Overall, these indices support the FCR7-C as a uni-dimensional model.

The results of Spearman's correlation generally support our assumptions (Table 3). The FCR7-C score had a low to moderate negative correlation with age, physical function, and QOL ($r = -0.33$, -0.31, and -0.30, respectively). A low positive correlation was observed for all individual symptoms except constipation. The FCR7-C score correlated positively with anxiety (high correlation; $r = 0.62$) and depression (moderate correlation; $r = 0.38$) (Table 3).

FCR severity

The total FCR severity score was 15.2 ($SD = 7.8$), indicating that these patients had mild FCR. No FCR was reported by 18.1% of patients across all 7 items, while the fraction of patients reporting significant FCR for items 1–7 was 19.4%, 18.8%, 19.4%, 6.3%, 11.9%, 20.6%, and 6.9%, respectively (Table 4).

Table 3 Correlation between FCR7-C and selected variables ($N = 160$).

Selected Variables	FCR7-C Total Score
Age	−0.33*
Performance Status	−0.31*
Overall QOL	−0.30**
Generalized Symptoms	
Pain	0.20**
Fatigue	0.43**
Nausea/vomiting	0.19*
Dyspnea	0.22**
Insomnia	0.29*
Lack of appetite	0.23**
Constipation	0.08
Diarrhea	0.21**
Anxiety	0.62**
Depression	0.38**

Data analysis: Spearman's correlation; *$p < 0.05$, **$p < 0.01$.

Discussion

In our cohort of 160 subjects, the FCR7-C was shown to have satisfactory content validity and internal consistency reliability. The uni-dimensional structure was supported by CFA that showed a good fit for the model. Consistent with our hypothesis, the FCR7-C score correlates positively with the degree of physical symptoms, anxiety, and depression, but correlates negatively with patient age, performance status, and QOL. We found that 81.9% of patients reported at least some FCR, with a mean FCR severity of 15.18.

Several important issues were clarified by this study. First, the satisfied internal consistency reliability of FCR7-C was supported by the high Cronbach's alpha of 0.90, which is comparable to that of the original FCR7 assessment.[6] All items except number 6 demonstrated high individual to total scale correlations (Cronbach's $\alpha = 0.72$–0.86). Item 6 had a moderate correlation (Cronbach's $\alpha = 0.45$).

Second, the results of CFA are generally acceptable to confirm the uni-dimensional structure of the FCR7-C, matching that of the FCR7[17] in a population of early-stage lung cancer patients. Although the good of fitness model was not perfect, the results after adjustment by MI suggest that the FCR7-C is acceptable. The potential reason for this lower fit is that item 6 has a relatively low item to total correlation. The content of item 6 is less similar than the other items in directly assessing the level of fear of cancer recurrence. Rather, it assesses awareness of physical signs of recurrence, thereby only indirectly addressing psychological concerns. Since the awareness of physical signs of recurrence is a component of the construct of fear of cancer recurrence, the final CFA model is generally acceptable after adjustment. Thus, we accept the notion that FCR7-C has a uni-dimensional structure.

All of the empirically based hypothesized assumptions were fully supported by our data, which are consistent with the findings of previous studies,[1,5–7,9,12,18,20,37] except that no significant correlation was observed between FCR severity and constipation. It might be because of constipation is not a major sign of lung cancer or its recurrence, this symptom may be less correlated to early-stage lung cancer patients. However, the other GI symptoms, diarrhea, has positive correlation with FCR. The possible reason might be that diarrhea is generally a symptom to reflect patients' anxiety. FCR might induce patients' anxiety and thus it is related to patients' diarrhea. More studies need to be explored to better understand the phenomena. Similar as previous study, fatigue has the highest correlation to FCR.[41] It supports that fatigue is the most robust symptom in triggering a patient's awareness of cancer recurrence.

Finally, for early-stage operable lung cancer patients, although not all patients reported concerns, 81.9% reported at least "a little" FCR. Furthermore, for each individual FCR7-C item, 6.3–20.6% of patients reported a significant level of fear of cancer recurrence. One-fifth of the subjects

Table 4 Severity of fear of cancer recurrence (N = 160).

	FCR7 Questionnaire	Not at all n (%)	A little n (%)	Sometimes n (%)	A lot n (%)	All the time n (%)	Significant FCR (%) 4–5
		1	2	3	4	5	
Q1	I am afraid that my cancer my recur	46 (28.7)	30 (18.8)	53 (33.1)	19 (11.9)	12 (7.5)	19.4
Q2	I am worried or anxious about the possibility of cancer recurrence	47 (29.4)	37 (23.1)	46 (28.7)	18 (11.3)	12 (7.5)	18.8
Q3	How often have you worried about the possibility of getting cancer again?	47 (29.4)	47 (29.4)	35 (21.8)	19 (11.9)	12 (7.5)	19.4
Q4	I get waves of strong feelings about the cancer coming back	97 (60.5)	38 (23.8)	15 (9.4)	7 (4.4)	3 (1.9)	6.3
Q5	I think about the cancer returning when I did not mean to	57 (35.5)	50 (31.3)	34 (21.3)	13 (8.1)	6 (3.8)	11.9
Q6	I examine myself to see if I have physical signs of cancer	60 (37.5)	36 (22.5)	31 (19.4)	24 (15.0)	9 (5.6)	20.6

		Not at all										A great deal	Significant FCR (%) 7–10
Q7	To what extent does worry about getting cancer again spill over or intrude on your thoughts and activities	0 79 (49.3)	1 18 (11.2)	2 15 (9.4)	3 13 (8.1)	4 6 (3.8)	5 16 (10.0)	6 2 (1.3)	7 6 (3.8)	8 4 (2.5)	9 0 (0.0)	10 1 (0.6)	6.9
	FCR-C (0–40)	Mean (SD) 15.2 (7.8)											

(20.6%) experienced a significant level of FCR in their response to item 6 (I examine myself to see if I have physical signs of cancer). These results strongly suggest that FCR is still an issue for early-stage lung cancer patients, indicating that screening for FCR among these is needed to provide further interventions to decrease patient distress and the number of outpatient department and emergency room visits.[13]

Conclusions

This study is the first study to develop and examine the Chinese version of FCR7 in early-stage lung cancer patients. The results strongly indicate that the FCR7-C is a very brief, easily used, and psychometrically valid tool. This assessment can be used to evaluate the severity of FCR in early-stage lung cancer patients, even in very busy outpatient care settings. Thus, we strongly recommend the systematic use of the FCR7-C as a screening tool for cancer patients in Chinese speaking patients as a basis for providing personalized psychological interventions.

Study limitations

Although this study indicates that the FCR7-C is a psychometrically valid tool, it still has some limitations. First, this study only includes cross-sectional data. Further study is needed to examine the test-retest reliability of FCR7-C. Second, majority of subjects in this study are diagnosed as lung cancer from health screening. Thus, we did not compare the differences among stages (I-IIIa) due to limited subjects in stage II and IIIa. Lack of sufficient subjects in each group might limit the power of statistical analysis and decrease the accuracy of results. Finally, the applicability of the FCR7-C to different cancer populations must be established.

Clinical implications

Our results suggest that FCR7-C is a brief assessment to use for screening cancer patients for FCR in clinical settings in Taiwan. Integrating the brief FCR7-C into hospital information system to screen patients' FCR is strongly

suggested. We also suggest to integrate the assessment into cancer care case management system. Thus, health care professionals can provide more personalized interventions to support those with high fear of cancer recurrence.

Data availability statement

The data to support the findings of this study are available from the corresponding author upon reasonable request.

Declaration of Competing Interest

The authors declare no conflicts of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jfma.2019.10.007.

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